Manual for the Completion of caBIG™ Case Report Form (CRF) Modules

Introduction

In 2006, members of the Cancer Biomedical Informatics Grid or caBIG™ in conjunction with the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into three categories:

- Mandatory – must be included when this data is collected for reporting
- Conditional – there are business rules to indicate situations under which this element should be used on a CRF
- Optional – no requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data, this is the element to include on the CRF

A template form with modules that contain questions or variables representing data to be collected was developed. The companion eCRF instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc.

Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

NCI Standard Medical History Module Template Instructions

Field Descriptions and Instructions

Field Name/Status	Description/Instructions	Format
Medical History Date (m)	Enter the date the medical history is collected.	Use prescribed date entry format.
Description (m)	Enter description of medical history at the time of collection.	Enter the Verbatim text
Ongoing (m)	Enter whether the medical history condition is ongoing at the time of collection.	Use choice list
Body System (o)	Enter the body system ***[Note: If this CDE is used then Finding Result, Description, and Ongoing are all Mandatory]***	Use choice list
Other Body System/Site Text (o)	Enter description of other body system/site.	Enter the name of the other body system/site.
Finding Result (o)	Enter the result of the assessment for a particular body system.	Use choice list

NCI Standard Medical History Module Template

Mandatory Questions

Medical History Date

Exchange Format: YYYYMMDD

[CDE Public ID and Version 2179659v2.0: The date a medical history was taken.]

Description

Text field – Maximum length = 200

[CDE Public ID and Version 2003874v3.0: Brief description of major medical and surgical events that occurred during the patient's lifetime.]

Ongoing

Yes
No
N/A

[CDE Public ID and Version 2736881v1.0: The indicator used to represent continuation of a medical event or symptom experienced by a person.]

Optional Questions

Body System

Abdomen
Allergy/Drug Sensitivity
Appearance
Body as a Whole
Breasts
Cardiovascular
Central Nervous System
Chest
Constitutional
Dermatologic
Endocrine
Endocrine/Metabolic
Extremities
Gastrointestinal
Genitalia
Genitourinary
H/E/E/N/T
Hematologic
Hematopoietic/Lymph
Hepatic
Immune
Integumentary/Hair
Musculoskeletal
Neck
Neurologic
Other
Pelvis
Peripheral Vascular
Psychiatric
Psychologic

Pulmonary
Rectal
Renal
Reproductive History
Respiratory
Spleen
Substance abuse/Dependency
Transfusion History
Urinary

[CDE Public ID and Version 2002895v4.0: An anatomic structure that consists of all members of one or more organ subclasses; these members are interconnected by anatomical structures or body substances.]

Other Body System/Site

Text field – Maximum length = 200

[CDE Public ID and Version 2182671v1.0: The text that describes the other specific organ system or body site.]

Finding Result

A = Abnormal
C = No Change
E = Equivocal
G = Negative
I = Improving
L = Not Applicable
N = Normal
O = No Source Data
P = Positive
S = Stable
U = Unstable
V = Not Evaluable
W = Worse
X = Not Examined
Z = Not Assessed

[CDE Public ID and Version 2003876v3.1: Response represents summary findings for the evaluation of a body system/site as normal (N), abnormal (A), not examined (X), or other enumerated values.]

End of Medical History Module